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Cancer treatment-related fatigue is recognized as a significant and long-lasting problem that effects patients both physically and emotionally and influences their treatment decisions and long-term recovery. The purpose of this study is to test the direct and indirect relationships of exercise to cancer treatment-related fatigue and quality of life in women with breast cancer receiving adjuvant chemotherapy. Thirty-one subjects have been enrolled in the 8-week home based exercise study. Subjects receive weekly telephone follow-up calls to remind them to return exercise logs and collect data on cancer treatment-related fatigue, symptoms, and affect. No adverse events have been observed, and subject recruitment is progressing as planned.

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Introduction:

Cancer treatment-related fatigue (CRF) is recognized as a significant and long-lasting problem that affects patients both physically and emotionally, and influences their treatment decisions, and long-term recovery. The specific aims of this study are to test the direct and indirect relationships of exercise to CRF and quality of life using latent variable modeling.

The majority of cancer patients report feelings of tiredness and fatigue during and after chemotherapy, with some citing it as a reason for prematurely ending treatment (Blesch et al., 1991; King, Nail, & Kramer, 1985; Knopf, 1986; Winningham et al, 1994). For this reason, it is critical to understand how exercise, CRF and quality of life during treatment interact to maintain or restore patients to pretreatment functional levels. Previous research suggests that exercise may help prevent the sequella of reduced functional capacity, nausea, fatigue, decreased self-esteem and other quality of life issues that confront cancer patients (Johnson & Kelly, 1990; MacVicar & Winningham, 1986, 1987; MacVicar, Winningham & Nickel, 1989; Mock et al, 1994; Mock 1997; Young-McCaughan & Sexton, 1991). Exercise is, in most cases, a neglected area of the treatment plan. However, exercise may slow the process of weakness, fatigueability and debilitation that affects many cancer patients. This pattern of fatigue, loss of self-esteem, inability to perform activities of daily living and maintain social relationships and employment has a profound effect on patients' quality of life. Based on this evidence, this study, examining the effects of exercise on fatigue and quality of life, is timely.

Methods:

A quasi-experimental, latent variable modeling design is being used to addresses the following research questions.

1. Are the proposed first order factors (exercise, fatigue and quality of life) adequately represented by their respective measures?
2. Does exercise have a direct and/or indirect effect on quality of life in women with breast cancer?
3. What is the pattern of fatigue in women with breast cancer who exercise?

At the end of Year 01, 31 subjects have been recruited. The projected sample of 78 women with breast cancer will be recruited in Years 02 and 03.

Procedures:

All subjects who meet eligibility criteria are invited to enter the study before they begin chemotherapy. Subjects receive an explanation of the purpose of the study and instructions regarding how to follow the home-based low intensity exercise program. After informed consent is obtained, baseline measures are recorded. These include a demographics questionnaire, 12-minute walk, visual analog scale of fatigue (VAS-F), Profile of Mood States (POMS) vigor-activity and fatigue-inertia subscales, Schwartz Cancer Fatigue Scale (SCFS) Quality of Life Index for patients with breast cancer (QOL Index), Positive and Negative Affect Scale (PANAS), and Symptom Side Effect Checklist (SESX). Subjects receive a packet containing materials for daily records of VAS-F and physical activity; and 7 pre-addressed, stamped envelopes to return the data to the University of Utah College of Nursing at the end of each week. Subjects also receive instruction on exercise intensity, duration and frequency, and use of the Caltrac™ monitor. During chemotherapy subjects are asked to avoid exercising in the 24-hours immediately following treatment. Subjects are followed for 8 weeks by

telephone. The weekly follow-up phone calls are used as a means to re-administer the POMS, SCFS, PANAS, and SESX; and to review the exercise prescription with the subjects Posttest measures are obtained in the 9th week, before the next chemotherapy cycle, on all data measurement except demographics.

Results:

In Year 01 of this study 31 women with breast cancer receiving adjuvant chemotherapy have been enrolled on the study. Four subjects have withdrawn for reasons related to being too busy, or were lost to follow-up. There have been no adverse events related to the study.

Data entry is being conducted on a regular basis. Programs for data analysis have been written and pilot tested. Results of preliminary testing of the data analysis programs indicate they run smoothly. The results of this preliminary testing, with 27 completed subjects, indicted variance in all the study variables (Table 1). Among subjects recruited to date 60% are adhering to the exercise program.

Table 1. Descriptive statistics for all measures (n=27 completed cases).

	Minimum	Maximum	Mean	Standard Deviation
Baseline 12-min walk[a]	2661	4905	3702.58	474.73
Posttest 12-min walk	1763	5747	3685.04	782.22
% change 12-min walk	63.33	123.5	99.72	16.45
Exercise Adherence	.06	9.13	1.54	1.76
Exercise Intensity	.11	28.02	1.85	6.53
Caltrac baseline [b]	35	236	59.81	35.25
Caltrac posttest [b]	36	114	59.62	19.92
SCFS total baseline	6	30	11.32	5.17
SCFS total posttest	6	26	11.72	5.03
SCFS physical baseline	3	15	5.71	2.62
SCFS physical posttest	3	15	6.20	2.63
SFS subjective baseline	2	15	5.16	2.88
SCFS subjective posttest	3	15	6.04	2.75
POMS fatigue baseline	0	28	7.48	6.11
POMS fatigue posttest	0	28	9.12	7.59
POMS vigor baseline	2	27	14.19	6.79
POMS vigor posttest	1	30	12.80	7.62
VAS-F average baseline	1	70	31.90	19.44
VAS-F average posttest	3	82	41.09	24.92
VAS-F worst baseline	0	97	43.57	27.18
VAS-F worst posttest	3	93	58.41	27.59
QOL Index baseline	33.65	84.35	61.41	10.87
QOL Index posttest	28.52	76.87	56.80	10.53

[a] 12-minute walk measured in feet.

[b] Caltrac recording of calories expended in activity mode.

Discussion:

Preliminary results indicate that the exercise intervention is acceptable to subjects. Recruitment into the study has been successful, with only 4 prospective subjects refusing to participate for reasons related to distance from the study site and work or family obligations. Retention of subjects in the study is encouraging; to date only 4 subjects have withdrawn. Subjects who engage in the exercise program report finding the program easy to follow and that the study design is not burdensome.

Results of this study will provide information about the effect of exercise on CRF and quality of life, and the pattern of CRF in women with breast cancer who exercise. This information is critical to the development of interventions to control or minimize CRF in cancer patients.

Recommendations in Relation to Statement of Work:

The tasks proposed for Year 01 have been a successfully met.

1. An independent study class in multivariate analysis and latent variable modeling was successfully completed.
2. The study was begun.
3. Subject recruitment, enrollment, and data collection are ongoing.

At the beginning of Year 02, no revisions to the Statement of Work are recommended. The project is progressing as planned.

Conclusions:

The strides made in Year 01 of this study shows that the study is progressing in the expected time frame and that the tasks are being carried-out as planned. No adverse events have been observed and study recruitment and retention is proceeding as planned. Measures used to capture the key variables appear to be capturing variance in each of the variables. Analysis with latent variable modeling is inappropriate at this time because of the small sample size. This analysis will be conducted at the conclusion of the study when their is an adequate sample size.

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